

FIG. 1

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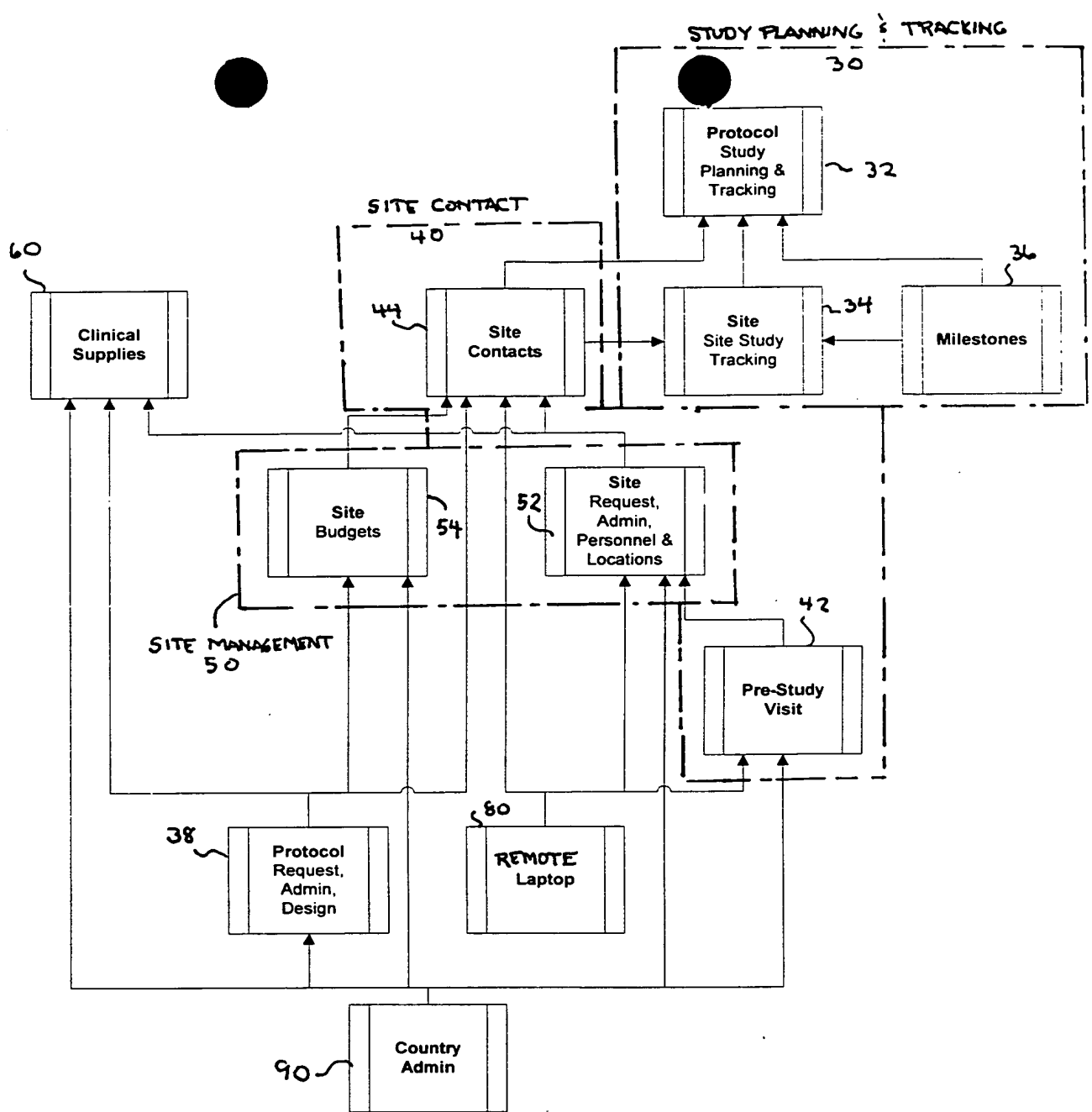


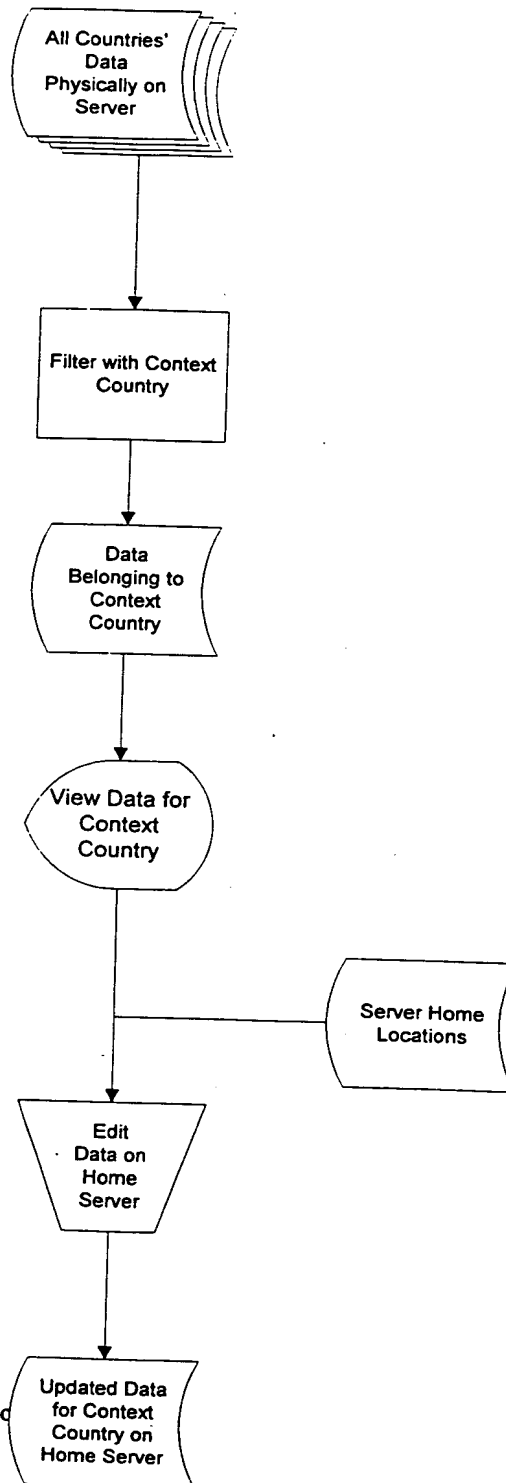
FIG. 2

## Data Flow Diagram

Module: Architecture

Section: Multi-Country

Fig. 3



## THE PROTOCOL NUMBER REQUEST SCREEN

PROSIT - Never Never Land

File Edit View Actions Module Window Help

Protocol Request

Site Administration Design Study Planning Study Tracking

Request ID	Subsite	Date	Protocol	Request	Physician	Protocol Number	Protocol Title
RQ - 0000001	01-MAR-15		Land	Pan, Peter J.	Darling, Wendy	- 000012	Mometasone vs. Budesonide in Asth
RQ - 0000002	26-MAR-15		Land	Pan, Peter J.	Darling, Wendy	- 000065	Mometasone vs. Budesonide in Asth
RQ - 0000003	26-MAR-15		Land	Pan, Peter J.	Darling, Wendy		Comparative Study of Topical Cortic
RQ - 0000004	26-MAR-15		Land	Pan, Peter J.	Darling, Wendy		Effects of rHuL-10 on Cytochrome P
RQ - 0000005	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Medicine, Chief		Absorption, Metabolism and Excretio
RQ - 0000006	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy		Endometrial Histologic Effects of Ora
RQ - 0000007	26-MAR-1998	RETURNED	Never Never Land	Pan, Peter J.	Medicine, Chief		Comparison of Mometasone Furoate
RQ - 0000010	31-MAR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Medicine, Chief	- 000112	Comparison of Mometasone Furoate
RQ - 0000079	03-APR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy		Mometasone
RQ - 0000080	08-APR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Darling, Wendy	- P00008	Mometasone vs Budesonide in Asthr
RQ - 0000103	07-MAY-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy		nge ipgo3kap3

Protocol Request

5/8/98 9:20:23

Fig. 4

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PROSIT - UNITED STATES

File Edit Actions Modules Window Help

Protocol Number Request Details [New]

Request No: Submit Date: Status: NEW

Schering No: Schering Name:

Requester: Rispoli, Marc C SPRI US IND: ☐

Project Physician: International: ☐

Program:

Mkt. Dose Form:

Project Accounting Code:

Monitoring Area:

Expense Center: 1477 - RESEARCH SYS

Phase:

Protocol Type:

Working Title:

FIS 5

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PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Protocol Administration: I - P00324

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Working Title: testing the new Prosit build version 1.04

Administration Personnel External Organizations

Protocol Status

Protocol Status: Amendment In Progress Study Status: PLANNED Active: F

Finalize Date: 04-NOV-1998 Notification: Notif. Date:

Notif. Reason:

Administration/Accounting

Therapeutic Team: Expense Center: 1477 - RESEARCH SYS

Program: INTERNATIONAL ALLERGY Mid. Dose Form: ALKM SPRNJ

Project Acct. Code: F01 - 000049 - 303E Originating Sub: UNITED STATES

Monitoring Area: MEDICAL AND SCIENTIFIC AFFAIRS Amend. Version: 1 Event Manager: F

Protocol Type: I - MEDICAL RESEARCH INTERNATIO Final Amend. Date:

The name of an outside organization or company that is working with SP on some aspect of the study

05-Jan-1999

Fig. 6

## EMPLOYEE ROSTER SCREEN

PR0SIT - Never Never Land

File Edit Actions Modules Window Help

Employee [View]

Employee Id:

Last Name:

Gender: Training. Fourteen

Country: Training. Nine

Contact Inform: Training. One

Phone No: Training. Seven

E-Mail Addr: Training. Six

Expense Chr: Training. Ten

Active: ☐

First Name:  M.I.

Title:

Fax No:

Mail Stop:

Type:

Physician: ☐

Ready

4/2/98 16:23:59

Figs. 7

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## PROTOCOL DESIGN

APROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol Design: 000065

Protocol: 000065 Schering No: 1032088 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Working Title: Mometasone vs. Budesonide in Asthma

Protocol Title: Efficacy and safety of mometasone furoate dry powder and budesonide powder (pulmicort turbuhaler) in the treatment of asthma

Primary Indication: 493 ASTHMA

IND/MA Ref No: Phase: PHASE III

Study Population: ADULTS

Data Collection Tool: CRF

Synopsis:

Salbutamol MDI acceptable for reversibility

Secondary Indications:

493.0 EXTRINSIC ASTHMA

493.1 INTRINSIC ASTHMA

This is a brief summary of the protocol

4/3/99 13:19:30

A.S.f

09555667-090600



## THE MEDICATION TAB

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol Design: 000065

Protocol: 000065 Schering No: 032068 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Test Drug Number Test Drug Name Role Amendment ID

032068 MOMETASONE PRIMARY

Test drug number can not be modified once saved, to change a test drug number delete it and re-add it.

Strength	Regimen	Dose Form	Route	Amendment ID
100 mcg	2x daily	INHAL PWD	INTRANASAL	
200 mcg	2 on 4x daily	INHAL PWD	INTRANASAL	

4

Ready

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# VISIT MAP

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol Design: 000065

Protocol: 000065 Schering No: 032008 Schering Name: MONETASONE

Working Title: Monetasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Visit ID	Visit Label	Study Phase	Prev Visit ID	Date Since Prior Visit	Enrollment	Amendment
				Min Max	Visit	ID
1	Test Recruitment	SCREENING		0 0		
2	Baseline	TREATMENT	1	7 14		
3	1st Evaluation	TREATMENT	2	5 9		
4	2nd Evaluation	TREATMENT	3	5 9		
5	Final Evaluation	FOLLOW-UP	4	25 31		
6	1st Evaluation Short	TREATMENT	2	7 14		
7	Final Evaluation Short	FOLLOW-UP	6	25 31		
8			7			

This is a descriptive label for the visit

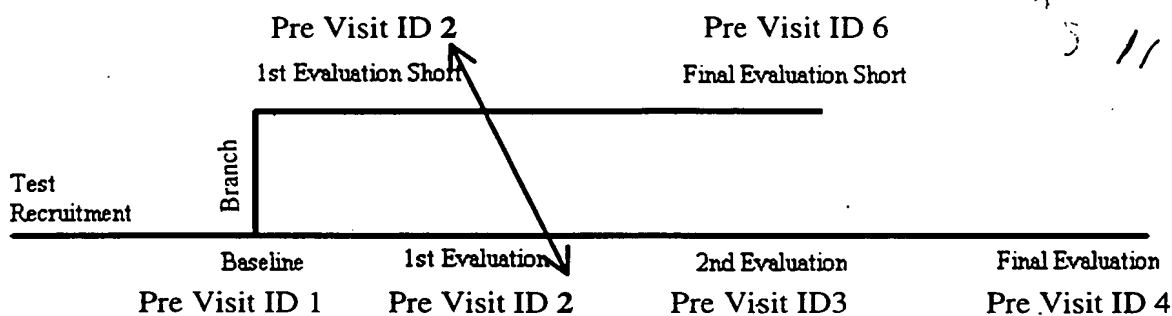
4/3/98 13:39:00

TS10

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## DIFFERENT TREATMENT SCHEDULES CONT.



## PROCEDURES TAB

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol Design: \* - 000065

Protocol: 000065 Schering No: 032088 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Treatment Schedule: Treatment Schedule 1

Procedure Name	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
LABORATORY EVALUATION	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEDICAL HISTORY	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VITAL SIGNS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
PHYSICAL EXAMINATION	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ECG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This is the label for identifying the study treatment

4/3/98 16:04:40

F.S. 12

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## OPTIONAL FIELDS

PRDSIT - NEVER NEVER LAND

File Edit View Options Modules Window Help

Protocol Design: - 000065

Protocol: 10000 Schering No: 032088 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Subject Optional Field Name	Data Type	Visit Optional Field Name	Data Type
HEIGHT	Decimal	ASTHMA SEVERITY	Integer
AGE ASTHMA ONSET	Integer	TREATMENT RESPONSE CORE	Integer
CONCOMITANT MED WASHOUT	Yes/No		

Ready

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T.S. 13

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## SUBJECT ELIGIBILITY

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol Design: P00008

Protocol: P00008 Schering No: 032086 Schering Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

**Reason for Ineligibility**

EXCLUDED CONCOMITANT MEDICATION ☐

DO NOT MEET ENTRANCE CRITERIA ☐

SUBJECT DOES NOT WISH TO PARTICIPATE ☐

EXCLUDED CONCOMITANT ILLNESS ☐

☐

**Reason for Discontinuation**

☐

DID NOT MEET ENTRANCE CRITERIA  
 DISEASE IS NOT SEVERE ENOUGH  
 DISEASE IS TOO SEVERE  
 EXCLUDED CONCOMITANT ILLNESS  
 EXCLUDED CONCOMITANT MEDICATION  
 HISTORY IS NOT APPROPRIATE FOR ENTRY  
 RECENT EXCLUDED HOSPITALIZATION OR PROCEDURE  
 SUBJECT AGE IS NOT APPROPRIATE  
 SUBJECT DID NOT RETURN FOR SCREENING  
 SUBJECT DIED PRIOR TO SCREENING

NC  
 DN  
 DS  
 EI  
 EM  
 HN  
 EH  
 SA  
 SS  
 SD

This is the reason why the subject would be considered ineligible

4/8/98 15:33:26

7.5.14

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## REASONS FOR DISCONTINUATION CONT.

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol Design: P00008

Protocol: P00008 Schering No: 032089 Schering Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION

PREGNANCY

DISEASE IS TOO SEVERE

Reason for Discontinuation

ADVERSE EVENT

PRE-ATRO

TREATMENT FAILURE, OVERALL DX STATUS MOD/SEVERE

LOST TO FOLLOWUP

INVESTIGATOR DEEMS IT IS NOT IN SUBJECTS BEST INTERES

NON-COMPLIANCE

DID NOT MEET PROTOCOL ELIGIBILITY

ADMINISTRATIVE	70
ADVERSE EVENT	10
CLEARED	80
COMPLETE	00
DEATH	99
DID NOT ENTER NEXT PHASE	51
DID NOT MEET CROSSOVER REQUIREMENTS	64
DID NOT MEET PROTOCOL ELIGIBILITY	60
DID NOT MEET PROTOCOL REQUIREMENTS	63
DID NOT MEET RANDOMIZATION CRITERIA	65

This is the reasons why a subject would be discontinued

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15.15

## DESIGN CONSIDERATIONS

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol Design: P00008

Protocol: P00008 Schering No. 032088 Schering Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Special Components

EFFICACY

BIOEQUVALENCY

Design Considerations

DOUBLE BLIND

ACTIVE COMPARISON

PARALLEL GROUP

RANDOMIZED

FOUR WAY CROSSOVER

LATIN SQUARE

NO TREATMENT CONTROL

OPEN LABEL

PARALLEL GROUP

PLACEBO CONTROL

PLACEBO WASHOUT

RANDOMIZED

SINGLE BLIND

THREE WAY CROSSOVER

This is the design component of the protocol

14/6/98 15:50:43

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Figs. 16



## CREATING AN AMENDMENT

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Refresh Finalize Protocol Amend Protocol

Protocol: 2008 Schering Name: MOMETASONE

Working Title: Event Manager

Administration Amendments Amendments Organizations

Protocol Status

Protocol Status: Finalized Study Status: **ENROLLMENT ONGOING** Active: ☒

Finalize Date: 12MAR1998 Notification: ☐ Notif. Date:

Notif. Reason:

Administration/Accounting

Therapeutic Tests: **ALLERGY/ASTHMA (ALLERGY II)** Expense Center: 5834-MGT. DEVEL & PLANNING

Program: LINE EXTENSION ALLERGY Mktg. Dose Form: ORAL POWD-GMP

Project Acct. Code: 001-032088-123G Originating Sub: UNITED STATES

Monitoring Area: MARKETING Amend. Version: Event Manager: ☒

Protocol Type: MEDICAL RESEARCH DOMESTIC CL Final Amend. Date:

Ready 13/12/98 13:45:08

Fig. 17

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PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Master Task List

Seq	Task Name	Task Type	Task ID	Milestone Indicator				
1	Completion of clinical program	SIMPLE	50					
2	Investigator Agreement Sent to HQ.	SIMPLE	23					
3	Curriculum Vitae of Principal Investigator(s)	SIMPLE	39					
4	CV of Laboratory Director(s) Received in S	SIMPLE	43					
5	Informed Consent Task(Trans)	SIMPLE	26					
6	Gov. Regulatory App. (w/Trans.) Received in S	SIMPLE	30					
7	CV of Laboratory Director(s) Received in Sub.	SIMPLE	34					
8	this is a new master task that was created by mark.fung-a-f	SIMPLE	439					
9	this is another very long task name that was created on the	SIMPLE	441					
10	Site Administration	SIMPLE	447					
11	Site Administration -Location/Personnel	SIMPLE	448					
12	Site Administration -Personnel and location	SIMPLE	457					
13	mark	SIMPLE	482					
14	Site Administration	SIMPLE	499					
15	First Data Discrepancy Report Available	SIMPLE	529					
16	Master Task Comm	SIMPLE	559					
17	First Subject/First Visit (Protocol)	SIMPLE	570					
18	Root	SIMPLE	70					
19	Design Start	SIMPLE	48					
20	Primary Stat Analysis Results Released	SIMPLE	15					

Rollup Task Name Type System ID

Ready 05-Jan-1999

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PROSIT - UNITED STATES

File Edit View Modules Window Help

Core Task List

Core Task List Core Site Instructions

Seq #	Name	Task Type Name	Milestone Indicator
1	Protocol Number Assigned	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
2	Final Protocol Date	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
3	Final CRF/RDE Screens Available	SIMPLE	<input checked="" type="checkbox"/>
4	First Site Initiated	SUMMARY	<input checked="" type="checkbox"/>
5	First Subject Enrolled (Protocol)	SUMMARY	<input checked="" type="checkbox"/>
6	First Subject First Visit	SUMMARY	<input checked="" type="checkbox"/>
7	Enrollment Cutoff (Protocol)	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
8	Last Subject / Last Visit (Protocol)	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
9	Last CDE/Data Discrepancy In-House	SIMPLE	<input checked="" type="checkbox"/>
10	Data Cleanup Complete (Protocol)	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
11	Database Locked	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
12	Primary Stat Analysis Results Released	SIMPLE	<input checked="" type="checkbox"/>
13	Final Statistical Results Released	SIMPLE	<input checked="" type="checkbox"/>
14	Final Data Listings Released	SIMPLE	<input checked="" type="checkbox"/>
15	Final PCS Date	SIMPLE	<input checked="" type="checkbox"/>
16	Last Data In-house/SPRI HQ (Protocol)	EVENT MANAGER SIMPLE	<input checked="" type="checkbox"/>
17	Last Site Initiated (to Date)	SUMMARY	<input checked="" type="checkbox"/>
18	(New)		<input type="checkbox"/>

A description of a task that will be mandatory for inclusion in every site plan in this country.

INCA 1000

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PROSIT - UNITED STATES

File Edit View Modules Window Help

Core Task List

Seq #	Task Name	Task Type	Milestone Indicator	TIA Indicator
24	Prestudy Visit Form(s) Received in Subsidiary	SIMPLE		
25	Prestudy Visit Form(s) Sent to HQ.	SIMPLE		
26	Protocol Signed by Investigator Rec. in Sub.	SIMPLE		
27	First Subject Enrolled (Site)	AUTOMATIC ROLL-UP		
28	Protocol Signed by Investigator Sent to HQ.	SIMPLE		
29	Site Initiated	AUTOMATIC ROLL-UP		
30	First Subject Screened	AUTOMATIC ROLL-UP		
31	All Data In-house (Site)	MANUAL ROLL-UP		
32	Written Ethics Committee App. (w/trans) Sent	SIMPLE		
33	Written Ethics Committee App. (w/trans.) Rec.	SIMPLE		
34	Data Clean-up Complete (Site)	MANUAL ROLL-UP		
35	Enrollment Complete (Site)	MANUAL ROLL-UP		
36	this is a new masker task that was created by mark fun	SIMPLE		
37	new requirement	SIMPLE		
38	Site Administration - Personnel and location	SIMPLE		
39	Site Administration	SIMPLE		
40	Site Administration	SIMPLE		
41	this is another very long task name that was created on	SIMPLE		
42	Milestone task added to check the duration	SIMPLE		
43	A master task with the milestone indic	SIMPLE		
44	(New)			

A description of a task that will be mandatory for inclusion in every site plan in this country

05-Jan-1999

1-8-20

PROSIT - UNITED STATES

File Edit Actions Modules Window Help

Template Tab Folder

Template: 1352 Changed: P (1352) Country: UNITED STATES

Name: Template to test the milestone indic change

Seq#	Task Name	Days	Task Type	Milestone Indicator	
1	USA-Template to test the milestone indic change		USER DEFINED		
2	Protocol Number Assigned	1	EVENT MANAGER S		
3	Final Protocol Date	0	SIMPLE		
4	Final CRF/RDE Screen Date	0	SIMPLE		
5	First Site Initiated	0	SUMMARY		
6	First Subject/First Visit (Protocol)	0	SIMPLE		
7	Enrollment Complete (Protocol)	0	EVENT MANAGER S		
8	Last Subject/ Last Visit (Protocol)	0	EVENT MANAGER S		
9	Data Cleanup Complete (Protocol)	0	EVENT MANAGER S		
10	Last Data Discrepancy Resolved	0	SIMPLE		
11	Database Locked	0	EVENT MANAGER S		
12	Primary Stat Analysis Results Released	0	SIMPLE		
13	Final Statistical Results Released	0	SIMPLE		
14	Final Data Listings Released	1	SIMPLE		
15	Final PCS Date	0	SIMPLE		
16	First Subject Enrolled	0	SUMMARY		
17	First Subject First Visit	0	SUMMARY		
18	Budget Info.Sheet (signed/dated by Inv.) Rec.	0	SIMPLE		

A unique number assigned by the system to identify the template

05-Jan-1999

Fig. 21

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## SELECTING A TEMPLATE

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: A-P00216 Schering No: 632000 Schering Name: MOMETASONE

Country: NEVER NEVER LAND Plan Status: DRAFT Plan Version: 0

Protocol Projections: 9/13/98 11:07:32

Select a Template

Template Name	Template ID
Allergy	691
Anti-infectives	695
CNS	697
Cardiovascular	696
Core Task Template	694
Dermatology	698
Oncology	699

Select Cancel

Ready 6/18/98 11:07:32

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Fig. 22

## PROTOCOL PROJECTION TAB

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Protocol: A - P00216 Schering No: 032068 Schering Name: MOMETASONE

Country: NEVER NEVER LAND Plan Status: DRAFT Plan Version: 0

Protocol Projections Study Planning Site Instructions

	Planned	Latest Est.
Evaluate Subjects	40	
Subjects to Enroll	50	
Sites NEVER NEVER LAND	2	
Sites International	0	
Sites Per Monitor	2	
Sites Per HQ CRA	0	
Monitoring Interval wks	6	
Min No Subjects Per Site	25	
Average Subjects Per Site	0	

Monitoring Countries	Planned	Latest Est.
NEVER NEVER LAND	0	0
<b>Totals</b>	<b>0</b>	<b>0</b>

Ready 6/18/98 11:09:21

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23

# STUDY PLAN

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: A-P00216 Schering No: 032000 Schering Name: MOMETASONE

Country: NEVER NEVER LAND Plan Status: DRAFT Plan Version: 0

Protocol Projections Study Planning Site Instructions

Seq	Task Name	Planned Start D	Planned End D	Planned Start M	Planned End M	Planned Start D	Planned End D	Planned Start M	Planned End M
1	RP00216 - NXL	18-JUN-1998	18-JUN-1998	0	0	18-JUN-1998	18-JUN-1998	0	0
2	Protocol Number Assigned	18-JUN-1998	18-JUN-1998	0	0	18-JUN-1998	18-JUN-1998	0	0
3	Protocol Approved	00-0000	00-0000	0	0	00-0000	00-0000	0	0
4	Investigators Identified	00-0000	00-0000	1	0	00-0000	00-0000	0	0
5	Pre-Study visits Conducted	00-0000	00-0000	1	0	00-0000	00-0000	1	0
6	Last Pre-Study Visit Report C	00-0000	00-0000	0	0	00-0000	00-0000	0	0
7	First Site Initiated	00-0000	00-0000	0	0	00-0000	00-0000	0	0
8	First Subject First Visit	00-0000	00-0000	0	0	00-0000	00-0000	0	0
9	Enrollment Complete (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
10	Last Subject/ Last Visit (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
11	All Data In-house (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results Re	00-0000	00-0000	0	0	00-0000	00-0000	0	0
14	Protocol Analysis Final	00-0000	00-0000	0	0	00-0000	00-0000	0	0
15	CSR Approved	00-0000	00-0000	0	0	00-0000	00-0000	0	0
16	(New)	00-0000	00-0000	1	0	00-0000	00-0000	0	0

Ready

6/18/98 11:15:05

F.S 24

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PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: P-P00124 Schering No: 000105 Schering Name: ESTRADIOL

Country: Never Never Land Plan Status: DRAFT Plan Version: 0

Study Planning | Site Instructions | Protocol Projections | SMP Study Plan | SMP Site Instructions

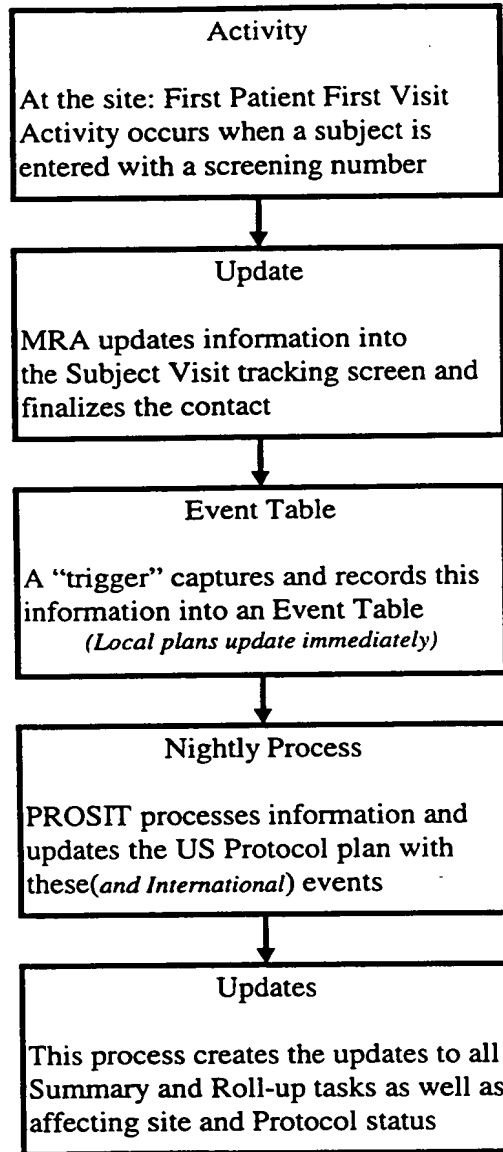
Seq	Task Name	Planned Start Dt	Planned End Dt	Planned Days	Planned Min Delay	Latest Start Dt	Latest End Dt	Latest Days	Latest Min Delay
1	P000124 - USA	12-AUG-1999	12-AUG-1999	0		12-AUG-1999	12-AUG-1999	0	
2	Protocol Number Assigned	12-AUG-1999	12-AUG-1999	0		12-AUG-1999	12-AUG-1999	0	
3	Final Protocol Date	00-0000	00-0000	0	0	00-0000	00-0000	0	0
4	Final CRF/EDC Screens Available	00-0000	00-0000	0	0	00-0000	00-0000	0	0
5	First Site Initiated	00-0000	00-0000	0	0	00-0000	00-0000	0	0
6	First Subject Enrolled (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
7	First Subject First Visit	00-0000	00-0000	0	0	00-0000	00-0000	0	0
8	Enrollment Cutoff (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
9	Last Subject / Last Visit (Proto	00-0000	00-0000	0	0	00-0000	00-0000	0	0
10	Last CIVE/Data Discrepancy In-Ho	00-0000	00-0000	0	0	00-0000	00-0000	0	0
11	Data Cleanup Complete (Protocol)	00-0000	00-0000	0	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results (Re	00-0000	00-0000	5	0	00-0000	00-0000	5	0
14	Final Statistical Results Released	00-0000	00-0000	0	0	00-0000	00-0000	0	0
15	Final Data Listings Released	00-0000	00-0000	0	0	00-0000	00-0000	0	0

The country whose plan will be viewed and/or edited

12-AUG-1999

F. 5. 25

## THE EVENT MANAGER



A.S. 26

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Module: Event Manager

PROSIT driven for:

- Planned/Protocol Number Assigned

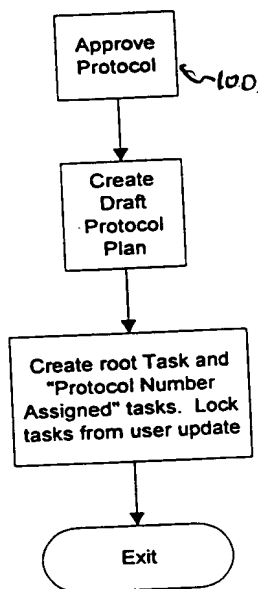


Fig. 27a

PROSIT driven for:

- Protocol Approved

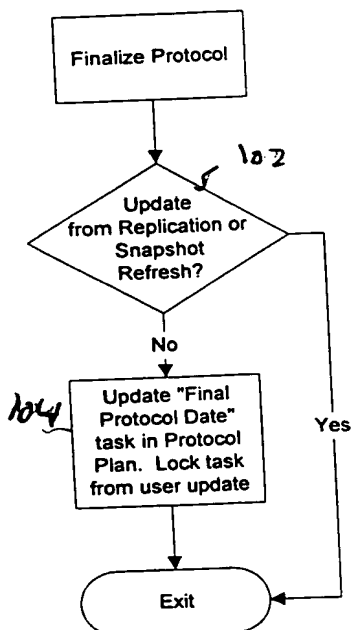


Fig. 27b

009060 090600 090600 090600

Module: Event Manager

PROSIT driven for:

- Initiated/1<sup>st</sup> Site Initiated & Site Initiated

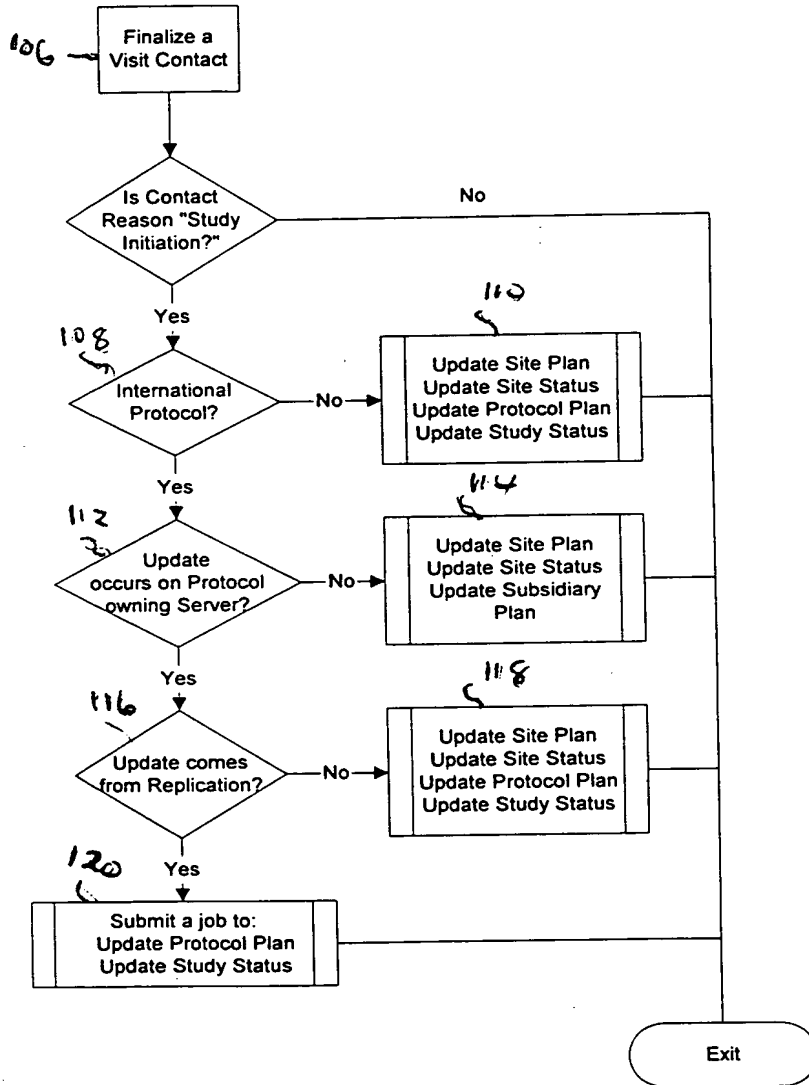


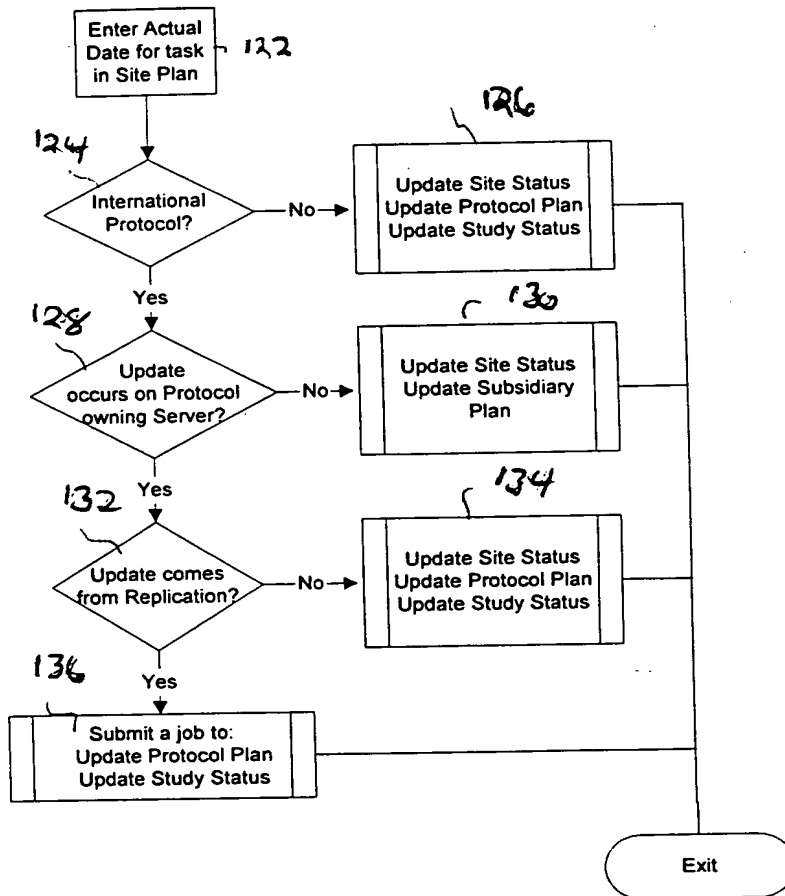
Fig. 27c

009060 2995960

# Module: Event Manager

Milestone (site level) driven for:

- Initiated/1<sup>st</sup> Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled



FS. 27d

009060" 2995960

Module: Event Manager

PROSIT and Milestone driven for:

- Last Site Initiated (to Date)

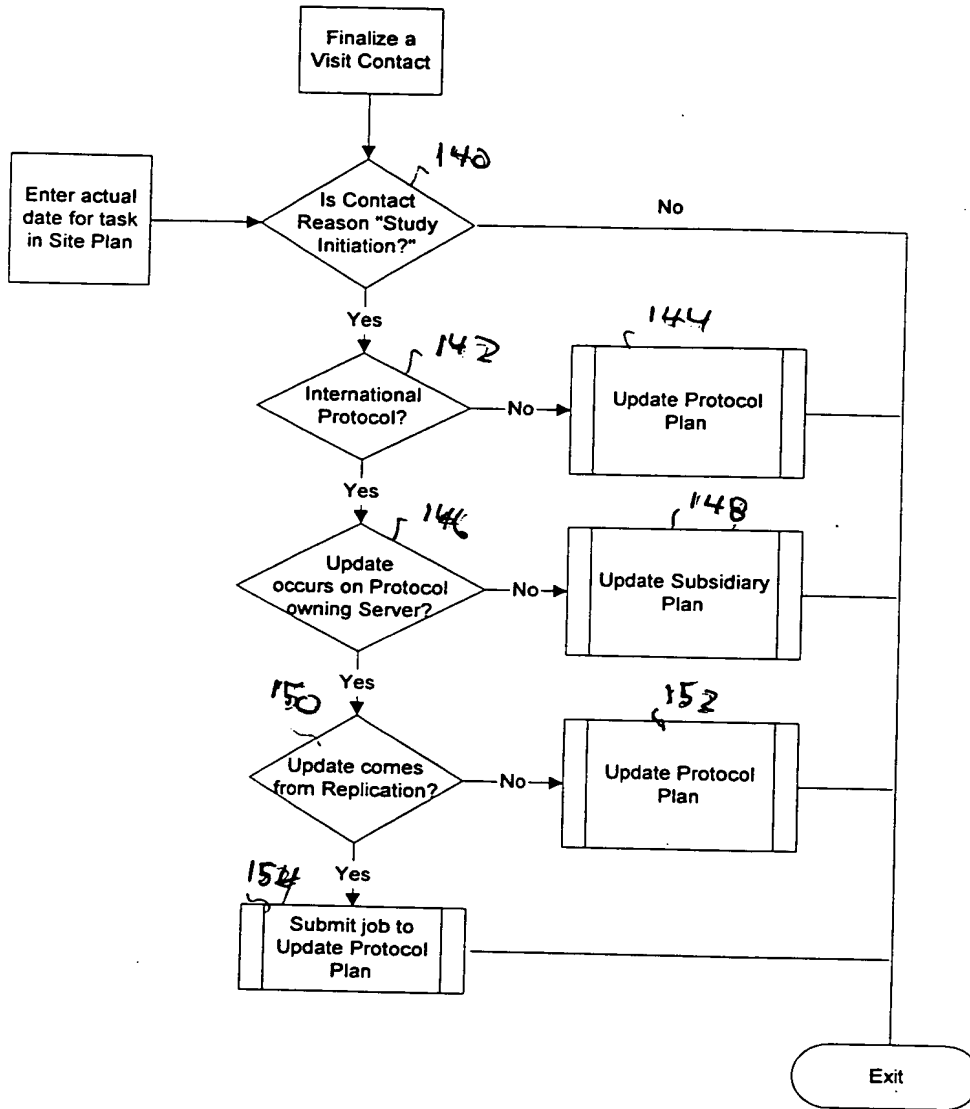


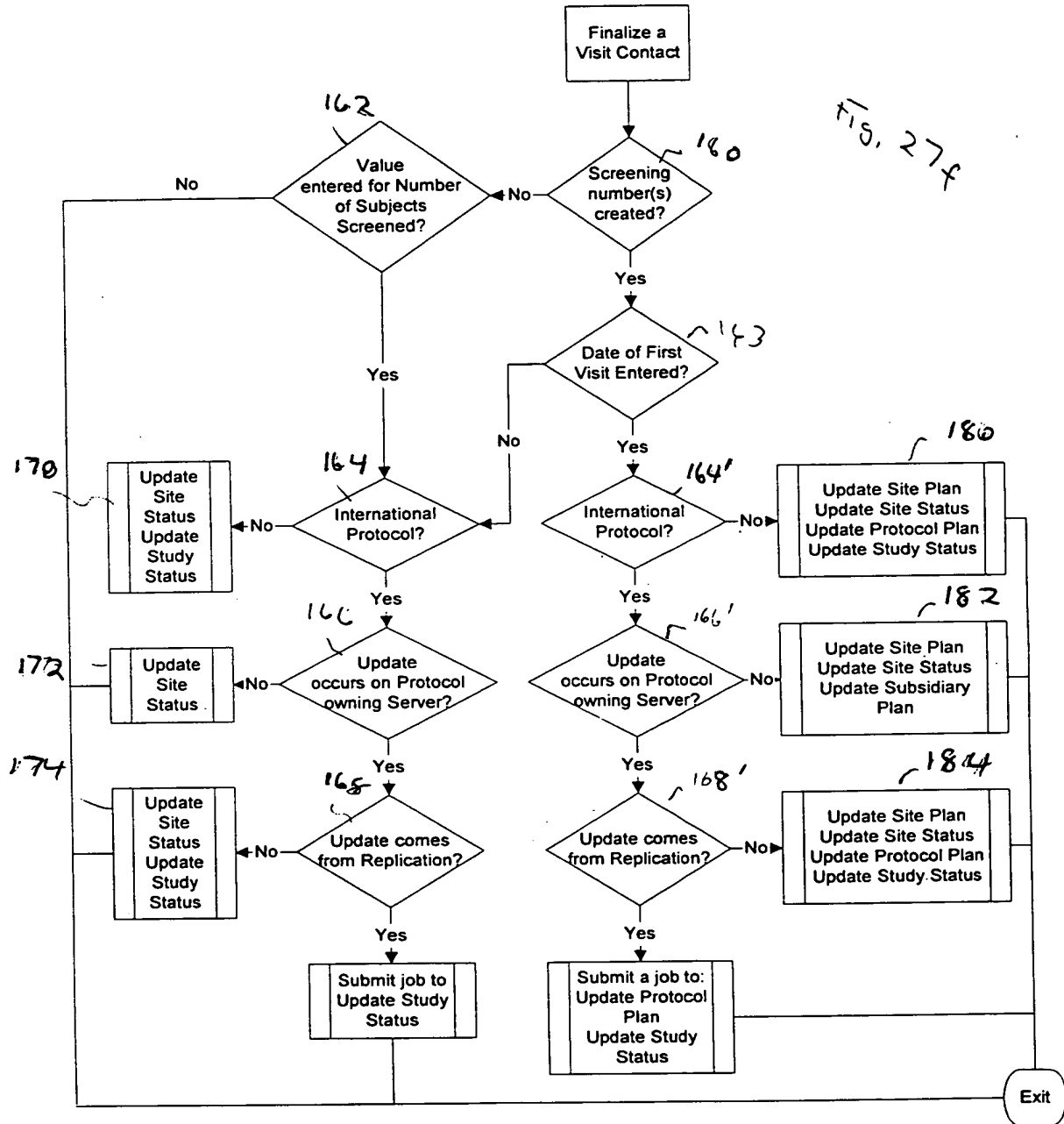
Fig. 27e

009060 0995960

# Module: Event Manager

PROSIT driven for:

- Screening Ongoing/First Subject, First Visit

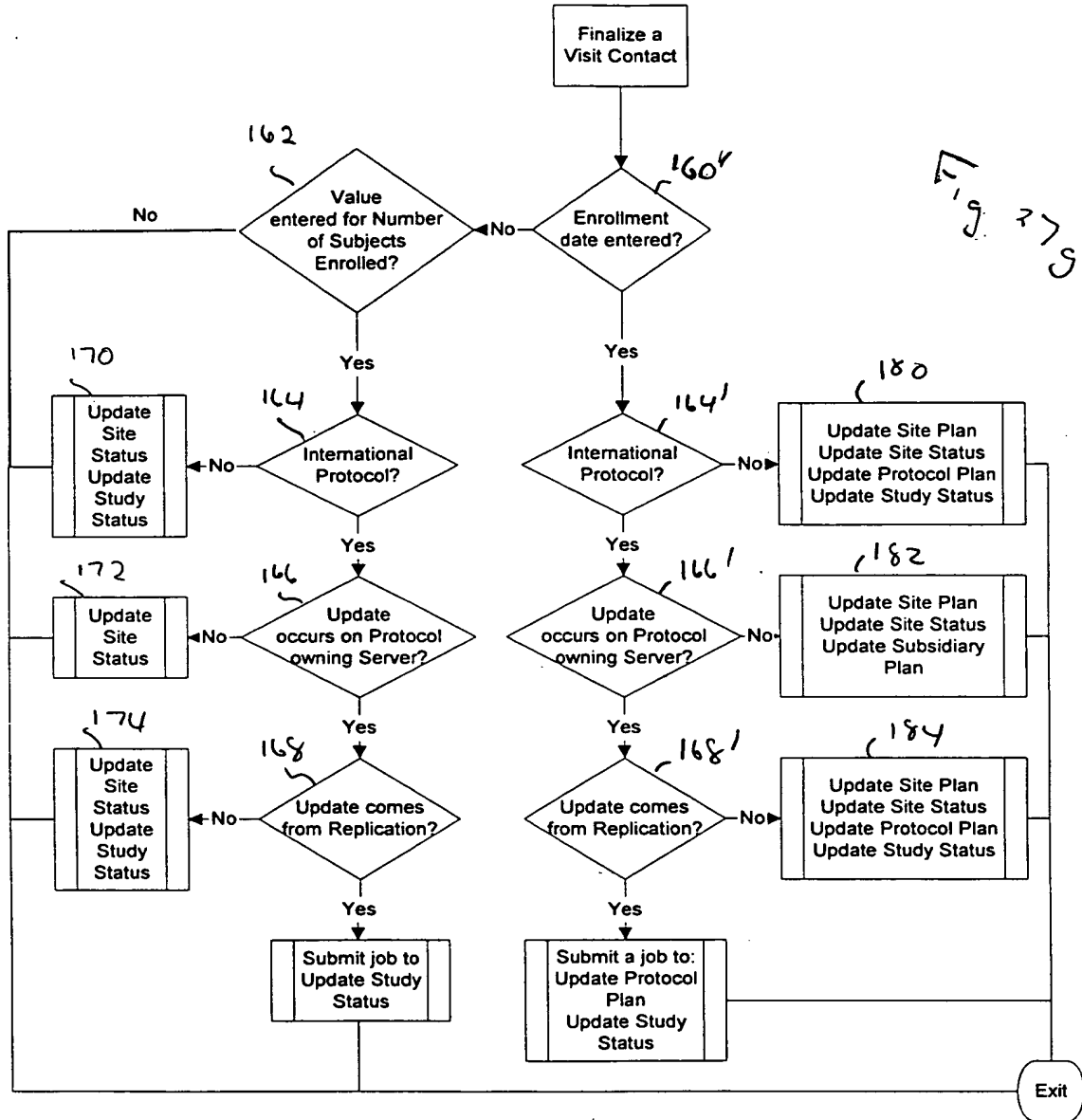


009060 49955600

# Module: Event Manager

PROSIT driven for:

- Enrollment Ongoing/First Subject Enrolled



009060 2995960



**Module: Event Manager**

Milestone (site level) driven for:

- Enrollment Complete
- Clinically Complete
- Site Closed

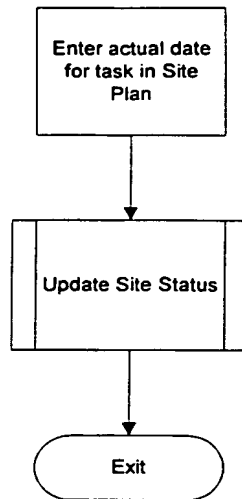


Fig. 27h

Milestone (protocol level) driven for:

- Initiated/1<sup>st</sup> Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled
- Enrollment Complete
- Clinically Complete
- All Data In-House
- Data Cleanup Complete
- Database Locked
- CSR Approved

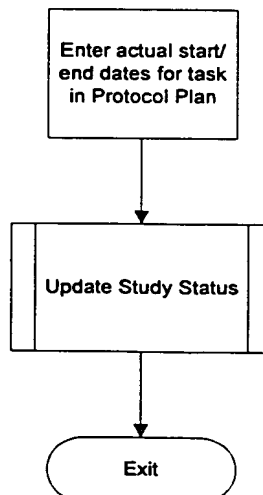


Fig. 27i

009060" 2995960

00655667 1090600

PROSIT - Never Never Land									
File Edit View Actions Modules Window Help									
Site Number Request									
Request No	Submit Date	Status	Country	Prior	Protocol	Site	Requestor	Investigator	Investig
RQ - 10293	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	1	Training, One	Investigator, One	Never Never Land
RQ - 10294	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	2	Training, Two	Investigator, Two	Never Never Land
RQ - 10295	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	3	Training, Three	Investigator, Three	Never Never Land
RQ - 10296	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	4	Training, Four	Investigator, Four	Never Never Land
RQ - 10297	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	5	Training, Five	Investigator, Five	Never Never Land
RQ - 10298	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	6	Training, Six	Investigator, Six	Never Never Land
RQ - 10299	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	7	Training, Seven	Investigator, Seven	Never Never Land
RQ - 10300	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	8	Training, Eight	Investigator, Eight	Never Never Land
RQ - 10301	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	9	Training, Nine	Investigator, Nine	Never Never Land
RQ - 10302	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	10	Training, Ten	Investigator, Ten	Never Never Land
RQ - 10303	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	11	Training, Eleven	Investigator, Eleven	Never Never Land
RQ - 10304	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	12	Training, Twelve	Investigator, Twelve	Never Never Land
RQ - 10305	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	13	Training, Thirteen	Investigator, Thirteen	Never Never Land
RQ - 10306	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	14	Training, Fourteen	Investigator, Fourteen	Never Never Land
RQ - 11047	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Hook, Captain	Never Never Land
RQ - 11048	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	1	Training, One	Hook, Captain	Never Never Land
RQ - 11049	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	2	Training, One	Bell, Tinker	Never Never Land
RQ - 11050	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Investigator, Eight	Never Never Land
RQ - 11067	28-DEC-1998	RETURNED	Never Never Land	B	P00100		Training, One	Bell, Tinker	Never Never Land
RQ - 11068	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11069	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Big Chief, Red	Never Never Land
RQ - 11070	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11071	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	1	Training, One	Bell, Tinker	Never Never Land
RQ - 11072	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	2	Training, One	Big Chief, Red	Never Never Land

Ready

7/15/99 11:19:38

Fig. 28

Fig. 29

PROSIT - Never Never Land - [Site Request Details (New)]

File Edit Actions Modules Window Help

Request No. Submit Date Status: NEW

Protocol: 4-000102

Requester: Training Six

Investigator:

Location: Never Never Land

Site Number:

Ready 7/16/99 14:38:26

09655667.090600

009060 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: Investigator: Abdulhoy, G Country: UNITED STATES

Site Administration | Post Study Eval.

Protocol  
Study Status: PLANNED Notification: RESUME STUDY

Notification Reason:

Site Status: PLANNED Effective Amendment: 1  
Data Collection Tool: CRF Effective Date: 04-NOV-1998  
Projected Enrollment  
Req. Minimum: 0 Site Enrollment: 1 Budget  
Procedure Level: Site Level

Prim. Location: YYYY  
Pre-study Visit: Currency: U.S. DOLLARS

Name	Function	Phone	Fax	Local Inv. No
Abdulhoy, G	PRINCIPAL INVESTIGATOR			

Ready 05-Jan-1999

Fig. 30

009060 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON

Site No: Investigator: Abdulhay, G Country: UNITED STATES

Site Administration Post Study Eval.

Global Assessment: NOT RECOMMENDED Evaluated By: Rispoli, Marc C

Evaluated On: 12-NOV-1998

ADEQUACY OF PATIENT SOURCE	GOOD	DRUG STORAGE AREA	ADEQUATE
FACILITIES	GOOD	LABORATORY	VERY GOOD
PRINCIPAL/CO-PRINCIPAL INVESTIGATOR	VERY GOOD	PIS TIME TO CONDUCT/SUPERV	VERY GOOD
STUDY STAFF	VERY GOOD	SUB INVESTIGATOR(S)	VERY GOOD

Ready

05-Jan-1999

Fig. 31

0095567-090500

**PROSIT - UNITED STATES**

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Schering No: 00000 Schering Name: ANTERON

Site No: Investigator: Abduhey, G. Country: UNITED STATES

Locations | SP Personnel | Non SP Personnel | Non SP Personnel Locations

Active	Primary	Location	Role	Country	Address
<input type="checkbox"/>	<input type="checkbox"/>	HELSINGIN YLIOPISTOLLINEN	(CO)SPONSOR	FINLAND	KESKUSSAIRAALA MEILAHENTIE 2
<input type="checkbox"/>	<input type="checkbox"/>	3V45_HSC_MCMMASTER_UNIV	CENTRAL IR	CANADA	This is address line 1 for external organization printing 1234567
<input type="checkbox"/>	<input type="checkbox"/>	410-2000 CREDIT VALLEY RD	CONTRACT	CANADA	MISSISSAUGA
<input type="checkbox"/>	<input type="checkbox"/>	SCICOR INC.	CENTRAL IR	UNITED STATES	8211 SCICOR DRIVE
<input type="checkbox"/>	<input type="checkbox"/>	kenilworth	CENTRAL IR	UNITED STATES	address
<input type="checkbox"/>	<input type="checkbox"/>	YYYY	CENTRAL IR	CANADA	YYYY
<input type="checkbox"/>	<input type="checkbox"/>				

Ready 05-Jan-1999

Fig. 32

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: Investigator: Abdulhay G Country: UNITED STATES

Locations: SP Personnel Non SP Personnel Non SP Personnel Locations

Active	Write	Employee	Responsibility	Active Date	Inactive Date	Country	Expense
<input type="checkbox"/>	<input type="checkbox"/>	Rispoli, Marc C	SITE REQUESTER	03-NOV-1998	00-0000	UNITED STATES	RESEAR
<input type="checkbox"/>	<input type="checkbox"/>	Lee, J S	CLINICAL DATA COORDINATOR	12-NOV-1998	00-0000	UNITED STATES	CHEMPR
<input type="checkbox"/>	<input type="checkbox"/>			05-JAN-1999	00-0000		

Name of a site staff person from the Non SP Personnel tab

05-Jan-1999

Fig. 33

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
 Site No: Investigator: Abdulhay, G Country: UNITED STATES

Locations: SP Personnel Non SP Personnel Non SP Personnel Locations

Active	Person	Responsibility	Active Date	Inactive Date	Country	Phone Number
<input checked="" type="checkbox"/>	Aapro, Mary S	PRINCIPAL INVESTIGATOR	03-NOV-1998	04-NOV-1998	UNITED STATES	908-603-3952
<input checked="" type="checkbox"/>	Aarons-You Ok, A L	DATA ENTRY CLERK/DATA COOR	04-NOV-1998	00- -0000	US VIRGIN ISLANDS	vhg.vb@cofid.k
<input checked="" type="checkbox"/>	Abdulhay, G	PRINCIPAL INVESTIGATOR	04-NOV-1998	00- -0000	UNITED STATES	234243-12341234-1
<input checked="" type="checkbox"/>	Aaronson, A L	DIETICIAN	12-NOV-1998	00- -0000	UNITED STATES	
<input checked="" type="checkbox"/>	Aaronson, D	HOSPITAL ADMINISTRATOR	12-NOV-1998	00- -0000	UNITED STATES	
<input checked="" type="checkbox"/>	6565656.6777775	CONTRACT/GRANTS ADMINSTR	12-NOV-1998	00- -0000	AMERICAN SAMOA	
<input checked="" type="checkbox"/>	Abbamont, T	IRB CHAIRMAN	12-NOV-1998	00- -0000	UNITED STATES	1234
<input checked="" type="checkbox"/>			05-JAN-1999	00- -0000		

Name of a site staff person from the Non SP Personnel tab

05-Jan-1999

Fig. 34



009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON  
 Site No: 1 Investigator: Abdulhay, G Country: UNITED STATES

Locations: SP Personnel Non SP Personnel Non SP Personnel Locations

Associated Site Personnel: Aaronson, D

Primary	Location	Role	Country	Address	City
<input checked="" type="checkbox"/>	SCICOR, INC.	CENTRAL IRB/EC	USA	8211 SCICOR DRIVE	IND
<input checked="" type="checkbox"/>	YYYY	CENTRAL LABORATORY	CAN	YYYY	YY
<input checked="" type="checkbox"/>	410-2000 CREDIT VALLEY	CONTRACT RESEARCH ORGANIZATION	CAN	MISSISSAUGA	ON
<input checked="" type="checkbox"/>	3V45 HSC MCMASTER	CENTRAL IRB/EC	CAN	This is address line 1 for external organization printing 1234567	HAI
<input checked="" type="checkbox"/>	HELSINGIN YLIOPISTO	(CO)SPONSORING ORGANIZATION	FIN	KESKIUSSAIRAALA MERIAHDENTIE 2	002
<input checked="" type="checkbox"/>	kenilworth	CENTRAL IRB/EC	USA	address	city
<input checked="" type="checkbox"/>					
<input checked="" type="checkbox"/>					

A check indicates that this is the primary location for contacting this site staff person

05-Jan-1999

Fig. 35

009060 29955960

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Site Study Tracking

Protocol: IP00324 Schering No: 000049 Schering Name: ANTERON  
Country: UNITED STATES Site: Investigator: Abdullah, G

Seq #	Task Name	Latest Date	Actual Date
1	IP00324-USA	00-0000	02-NOV-1998
2	Completed Grant Request Form Received in Sub.	00-0000	00-0000
3	CV of Laboratory Director(s) Received in S	00-0000	00-0000
4	Budget Info Sheet (signed & dated by Inv.) Rec.	00-0000	00-0000
5	CV of Laboratory Director(s) Received in Sub.	00-0000	00-0000
6	CV of Laboratory Director(s) Sent to HQ	00-0000	00-0000
7	Completed Grant Request Form Sent to HQ	00-0000	00-0000
8	Cumculum Vitae of Principal Inv(s) Rec. in	00-0000	00-0000
9	Cumculum Vitae of Principal Investigator(s)	00-0000	00-0000
10	Cumculum Vitae of Sub-inv(s) Received in S	00-0000	00-0000
11	Cumculum Vitae of Subinvestigator(s) Sent t	00-0000	00-0000
12	Doc of Quality Control Proc. or Cert. Rec. in	00-0000	00-0000
13	Doc of Quality Control Proc. or Cert Sent to	00-0000	00-0000
14	FDA Form 1572 Received in Sub.	00-0000	00-0000
15	FDA Form 1572 Sent to HQ	00-0000	00-0000
16	Gov. Regulatory App. (w/ trans.) Sent to HQ	00-0000	00-0000
17	Gov. Regulatory App. (w/trans.) Received in S	00-0000	00-0000
18	Informed Consent Task(Trans)	00-0000	00-0000
19	Informed Consent Doc. (with translation) Sent	00-0000	00-0000
20	Site Closed	00-0000	00-0000

The site whose tracking will be viewed/edited

05-Jan-1999

Fig. 36

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: Investigator: Abdulhey, G Currency: U.S. DOLLARS Revision: 1

Administration Site Payees Site Budget Subject Costs

Status:

Amendment:

Submit Date: 00- -0000

Effective Date: 00- -0000

Overhead Percent: 0.00

The label that identifies the name of the visit schedule selected. Procedures for the discontinuation visit are also budgeted here

05-Jan-1999

Fig. 37

09655667-090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: Investigator: Abdulhay, G Currency: U.S. DOLLARS Revision:

Administration Site Payees Site Budget Submit Costs

Local Payee	Global Payee	Finance Code
	10TH SYMPOSIUM MOLECULAR	

Ready 05-Jan-1999

Fig. 38

005567-090600

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: A-P00102 Schering No: 000001 Schering Name: STEROIDS FOR SKIN TESTS  
 Site No: 4 Investigator: Big Chief, Red Currency: GOURDE Revision: 1

Administration Site Payees Site Budget Subject Costs

Protocol: P00102 Site No. 4 Revision: 14N REVISION Effective Date: Amendment:

Line Item	OH Default Price	Unit Cost	Units	Total
<b>SUBJECT COSTS</b>				
<b>PROCEDURE COSTS</b>				
Laboratory Evaluation	<input type="checkbox"/> Captain Hook	10.00	5	50.00
Medical History	<input checked="" type="checkbox"/>	100.00	2	200.00
	<input type="checkbox"/>	.00		
<b>ADDITIONAL VISIT COSTS</b>				
Evaluation	<input checked="" type="checkbox"/> 10TH SYMPOSIUM	100.00	3	300.00
	<input type="checkbox"/>	.00		
<b>ADJUSTMENTS</b>				
Recovery	<input type="checkbox"/>	100.00	2	200.00
	<input type="checkbox"/>	.00		
<b>OTHER COSTS</b>				
Advertisement	<input type="checkbox"/> 10TH SYMPOSIUM	100.00	2	200.00
Discovery	<input type="checkbox"/> Captain Hook	20.00	3	60.00
<b>TOTAL BUDGET</b>				<b>1,060.00</b>
<b>PREVIOUSLY APPROVED</b>				
<b>REQUIRED</b>				

A description of the line item cost

12-Aug-1999

Fig. 39

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON  
 Site No: 1 Investigator: Abdukey, G Currency: U.S. DOLLARS Revision:

Administration | Site Payees | Site Budget | Subject Costs

Treatment Schedule: Treatment Schedule 1

Line Item	Subjects Budgeted >	1	2	3
13C-UREA BREATH TEST		\$00	\$00	\$00
12-LEAD ECG		\$00	\$00	\$00
2-VIEW XRAY		\$00	\$00	\$00
24-HOUR URINE COLLECTION		\$00	\$00	\$00
4-VIEW XRAY		\$00	\$00	\$00
		\$00	\$00	\$00

Ready 05-Jan-1999

Fig. 40

009060" 29955960

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pro-Study Visit

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aasebo, U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

Potential Investigator: Aasebo, U Potential Study Location: Location Name

Country: AFGHANISTAN

Visit Date: 18-NOV-1998 Time: 16:25 Finalized: 00-0000

Schering Participants:	Investigator Site Participants: Non-Registered(*)
Rispoli, Marc C	Aasebo, U

Ready 05-Jan-1999

Fig. 41

009060 0955567

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10556 Principal Investigator: Aasebo U Country: NORWAY

Pre-Study Visit | SP Personnel | NSP Personnel | Discussion Items | Evaluation

Registered Site Personnel

Name		Title
Aasebo U		

Non-Registered Site Personnel

Last Name	First Name	Title

This is a registered site person

05-Jan-1999

Fig. 42



009060" 29955960

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aaseba, U Country: NORWAY

Pre-Study Visit | SP Personnel | NSP Personnel | Discussion Items | Evaluation

STUDY CONSIDERATIONS	ETHICAL CONSIDERATIONS
<input checked="" type="checkbox"/> Pre Clinical Data	<input checked="" type="checkbox"/> Curriculum Vitae
<input checked="" type="checkbox"/> Clinical Data	<input checked="" type="checkbox"/> Principal Investigator
<input checked="" type="checkbox"/> Investigator Brochure	<input checked="" type="checkbox"/> Co-Principal Investigator
<input checked="" type="checkbox"/> Protocol	<input checked="" type="checkbox"/> Sub-Investigator
<input checked="" type="checkbox"/> Case Report Forms	<input checked="" type="checkbox"/> Lab Director
<input checked="" type="checkbox"/> Monitoring Responsibilities	<input checked="" type="checkbox"/> Laboratory Certification
<input checked="" type="checkbox"/> Study Schedule	<input checked="" type="checkbox"/> Laboratory Q.C. Procedures
<input checked="" type="checkbox"/> Principal Investigator Responsibilities	<input checked="" type="checkbox"/> Laboratory Reference Ranges
<input checked="" type="checkbox"/> Sub-Investigator Responsibilities	<input checked="" type="checkbox"/> DEA Regulations and Drug Control
<input checked="" type="checkbox"/> Staff Responsibilities	<input checked="" type="checkbox"/> Adequacy and Accuracy of Records
<input checked="" type="checkbox"/> Grant	<input checked="" type="checkbox"/> Availability of Patient Records
<input checked="" type="checkbox"/> Payment Schedule	<input checked="" type="checkbox"/> Drug Accountability and Disposition
	<input checked="" type="checkbox"/> IRB/EC
	<input checked="" type="checkbox"/> Approval Documents
	<input checked="" type="checkbox"/> Responsibilities
	<input checked="" type="checkbox"/> Retention of Records
	<input checked="" type="checkbox"/> Informed Consent
	<input checked="" type="checkbox"/> FDA 1572 OR
	<input checked="" type="checkbox"/> Investigator Agreement
	<input checked="" type="checkbox"/> Nature of FDA Inspection

Ready 05-Jan-1999

Fig. 43

009060 79955960

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aaseba U Country: NORWAY

Pre-Study Visit | SP Personnel | NSP Personnel | Discussion Items | Evaluation

Global Assessment: RECOMMENDED

ADEQUACY OF PATIENT SOURCE: GOOD DRUG STORAGE AREA:

FACILITIES: LABORATORY:

PRINCIPAL INVESTIGATOR/CO-PRIN: PTS TIME TO CONDUCT/SUPERVISE: VERY GOOD

STUDY STAFF: SUB INVESTIGATORS:

Ready 05-Jan-1993

Fig. 44

009060 29955960

PROSIT - UNITED STATES

File Edit Tools Actions Modules Forms Window Help

Visit Contact

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site No: 1 Contact: 00011286 - 04-Nov-1998 unfinalized

Visit Contact | Discussion Items

Contact Information

Originator: Rispoli, Marc C Reason: CLINICAL STUDY SUPPLIES

Date: 04-NOV-1998 Time: 00:00

Meeting Location

Site Roster: Testing the new prosit 1.03.1 build

Other:

Recommendation

The investigator site is: Recommended Not Recommended

Schering Participants

Rispoli, Marc C

Non-Schering Participants

Aspro, Mary S

Fig. 45

The study center that was involved in this contact

05-Jan-1999

0095060" 29955960

PROSIT - Never Never Land

File Edit Tools Actions Modules Forms Window Help

Electronic Mail Contact

Protocol:  Schering No: 032088 Schering Name: MOMETASONE

Site No:  Contact: 00008480 - 02-Aug-1999 unfinalized

Electronic Mail Contact | Discussion Items

Contact Information

Originator:  Reason:

Date:  Time:

Phone Contact Details

Outside Party Phone #:

Schering Participants

Butt, Thud

Non-Schering Participants

Ready

03-Aug-1999

Fig. 46

009060 29959960

**PROSIT - UNITED STATES**

File Edit Tools Actions Modules Forms Window Help

**Visit Contact**

Protocol:  Schering No: 000049 Schering Name: ANTERON

Site No:  Contact: 00011286 - 04-Nov-1998 unfinalized

Visit Contact Discussion Items

New Pre-Clinical or Clinical Data	Personnel Responsibilities	Clinical Supplies
<input type="checkbox"/> Efficacy	<input type="checkbox"/> Principal Investigator	<input type="checkbox"/> Quantity
<input type="checkbox"/> Adverse Events	<input type="checkbox"/> Sub-Investigator	<input type="checkbox"/> Storage
<b>Protocol Adherence</b>	<input type="checkbox"/> Staff	<input type="checkbox"/> Dispensing
<input type="checkbox"/> Subject Selection	<b>Facilities</b>	<input type="checkbox"/> Packaging/Labeling/Coding
<input type="checkbox"/> Conduct Of Study	<input type="checkbox"/> Location Of Patient Info.	<input type="checkbox"/> Randomization
<input type="checkbox"/> Adverse Events	<input type="checkbox"/> Clinical Laboratory	<input type="checkbox"/> Recertification Date
<input type="checkbox"/> Concomitant Medications	<input type="checkbox"/> Equipment	<input type="checkbox"/> Drug Disclosure Envelopes
	<input type="checkbox"/> Other	<input type="checkbox"/> Documentation of Accountability
<b>Case Report Form (CRF) Records</b>		<b>Monitoring Activities</b>
<input type="checkbox"/> CRF Completion vs. Patient Enrollment		<input checked="" type="checkbox"/> Action Taken By PI and Monitor to correct deficiency
<input type="checkbox"/> CRF Completeness		<input checked="" type="checkbox"/> Source Document Verification Completed
<input type="checkbox"/> CRF Availability, Storage and Retention		<input checked="" type="checkbox"/> Consents Reviewed
		<input checked="" type="checkbox"/> Source Document Checked

\* Required to finalize the site contact.

The study center that was involved in this contact

05-Jan-1999

Fig. 47

009060 29955960

PROSIT - UNITED STATES			
File Tools Actions Modules Window Help			
Site Tracking			
Protocol: I-P00324		Schering No: 000049	Schering Name: ANTERON
Site: 1	Contact: 11286	Visit: Unfinalized	As of: 01-Nov-1998
Enrollment Tracking		Ineligible For Screening	
Potential Subjects Ineligible for Screening:	<input type="text" value="2"/>	Enrollment as of Unfinalized Site Visit	Enrollment as of Latest Finalized Visit
Number of Subjects Screened:	<input type="text" value="10"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Number of Subjects Failed Screening:	<input type="text" value="2"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Number of Subjects Enrolled:	<input type="text" value="8"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Number of Subjects Discontinued total:	<input type="text" value="2"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Adverse Events:	<input type="text" value="1"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Other:	<input type="text" value="1"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Number of Subjects Complete:	<input type="text" value="5"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Number of Subjects Ongoing:	<input type="text" value="1"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

Fig. 48a

Ready

05-Jan-1999

09655667-090600

PROSIT - Never Never Land

File Tools Actions Modules Window Help

Site Tracking

Protocol: 000065 Screening No: 002068 Screening Name: MOMETASONE

Site: 1 Contact: 2656 Telephone: Unfinalized As of: 30-Mar-1998

Enrollment Tracking Ineligible For Screening

	Number of Subjects as of: 30-Mar-98	Percent of Site Total
Site Total:	0	
Reason For Ineligibility		
PREGNANCY	0	100.0
EXCLUDED CONCOMITANT MEDICATION	0	0.0
DEASE IS TOO SEVERE	0	100.0

Ready 4/8/98 11:46:02

Fig. 48b

009060" 79955960

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Subject Visit Tracking

Protocol: P00324 Site: 1 Contact: 11286

Screening Number: 1 Subject Number: E Initials:

Subject Visit Summary / Discout / Unshed / 1

Gender: MALE Date of Birth: 01-JAN-1971 Age of Enrollment: 27 Years

Signed Consent: 02-NOV-1998 Last Visit Number: 0 Discontinuation Visit:

Enrollment: 09-NOV-1998 Current Phase: MAINTENANCE

Therapy Started: 00-0000 Complete: / Useable/Evaluable: /

Therapy Ended: 00-0000 Reason For Discontinuation:

Days On Therapy: Discontinuation Date: 00-NOV-1998

Additional Subject Data:

SUBJECT 1:

Ready 05-Jan-1999

Fig. 49



009060" 79955960

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Subject Visit Tracking

Protocol: I-P00324 Site: 1 Contact: 11286

Screening Number: [ ] Subject Number: [ ] Initials: [ ]

Subject Visit Summary [X] Discort [X] Unshed [2] [1]

Visit No	Amendment	Visit Label	Visit Date	Delta	TO DO	CRF Status	SDV Status
1		Visit 1	09-Nov-1998		<input type="checkbox"/>	COLLECTED	<100%
2		Visit 2	16-Nov-1998	6	<input type="checkbox"/>	PARTIALLY COLLECTED	<100%
3		Unscheduled Visit	23-Nov-1998		<input checked="" type="checkbox"/>	PARTIALLY COLLECTED	
4		Discontinuation Visit	30-Nov-1998		<input checked="" type="checkbox"/>	NOT COLLECTED	

Ready 05-Jan-1999

Fig. 50

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Formulated Materials Requisition

FMR Req. ID: 184

Administration Materials

Protocol Information

Protocol Number: A-P-00240 Schering No: 000028 A AND D

Program Code: F05 Schering No: 000028 Marketed Dose Form: BOLUS

Expense Center: 1495 - WORLDWIDE RSCH QA

Requisition Source: ANIMAL HEALTH DOMESTIC/INTERNATIONAL

Requested by: Desantos, Marc

Authorized by: Desantos, Marc

Date Required For Packaging: 22-DEC-1998 Blinding Required: ☒

Special Directions and Blinding (explain blinding requirements if any):

A protocol under which the requested supplies will be utilized

05-Jan-1999

Fig. 51

009060" 49955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
Country: UNITED STATES PSR No: 1409

PSR Information Components Ship To

Project Accounting Code: F01-000049-303E Exp Center: 1477 RESEARCH SYS

New Protocol/Site: Study Type: ☒ Blind ☐ Open

Study Monitor: Gmrt PC

Random Code Format: CODE ENVELOPES

Requested by: Rispoli, Marc C

Authorized by: 3.3

Required Ship Date: 31-MAR-1999 Random Code Generation ID: Select Site:

IND Labeling Date: 00-0000

Attachments: ☒

PROTOCOL: ☒  
LABEL FORMAT: ☒  
LABELING INSTRUCTIONS: ☒  
DEA FORM 222C: ☒  
CONFIRMATION DEA REG. N: ☒

Special Instructions:

A number generated when the PSR is first saved to uniquely identify the PSR. This is not the PSR number generated by the clinic. 05-Jan-1999

Fig. 52

0955667-090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: C-C98005 Schering No: 032088 Schering Name: MOMETASONE  
Country: UNITED STATES PSR No: 11115

PSR Information Components Ship To

Schering No.	Schering Name	Test Dose Form	Strength/ concentration	Package Description/Fill	Required Units
032088	MOMETASONE	ORAL AERPR	UNKNOWN		

The Schering number of the drug that will be packaged.

11-24-1999

Fig. 53

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
Country: UNITED STATES PSR No: 1489

PSR Information Components Ship To

Location: SCHERING CANADA INC  
Address: 170 ONEIDA STREET  
City: POINTE CLAIRE US State/Other:  
Postal Code: H9R 1B4 Country: CANADA  
Phone: Fax: 514 426 7300  
Attention:

The subsidiary to which the clinical supplies will be shipped.

05-Jan-1999

Fig. 54

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE

Country: UNITED STATES Site No: 1 MTR No:

MTR Details Ship To:

Inventory Location: Requested Ship Date: 00-0000

Requested By: Caprio, Denise M

Authorized By:

Expense Center: 1751 SR DIR INTL CLIN RES Intended Use Of Material

Material Type	Batch No.	PSR No.	FMR No.	Quantity	Quantity On Hand
---------------	-----------	---------	---------	----------	------------------

The type of material to be shipped

114 Jun 1998

Fig. 55

527

009060" 29955960

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE  
Country: UNITED STATES Site No: 1 MTR No: AA000637

MTR Details: Ship To

Location:

Address:

City:  State/Province:

Postal Code:  Country:

Phone:  Fax:

Attention:

Shipping/Packaging Instructions:

The name of the person who will receive the shipment at this location.

Fig. 56

005060" 090600

**PROSIT - UNITED STATES**

File Edit Actions Modules Forms Window Help

**Random Code Request - New**

Protocol:  Schering No: 032088 Schering Name: MOMETASONE  
Random Code Req ID:  Date Prepared: 00-0000 Pctl Finalization Dt: 21-JUL-1999

To:  Copies:   
From:  Random Code Type:   
Generate Random Code by:

Number of United States Sites:  Random Code Generation ID:   
Number of International Sites:  First United States Site ID:   
First International Site ID:  Comments:

	Treatment Arm	Subjects
Subj Randomized by: <input type="text" value=""/>		
Subj Replaced by: <input type="text" value=""/>		
Subj nbr assigned by: <input type="text" value=""/>		
Number of Stratification: <input type="text" value=""/>		
Total Subjects:		0

Fig. 57

[A number generated when the RCR is first saved to identify the random code request memo.

11/1/99



009060" 29955960

PROSIT - UNITED STATES

File Actions Modules Window Help

Check Control

Userid: **RENOWSKI** Renowski, George

Check Out

Date: 13-Jul-1999 Extra Items ☐ Status: Checked out data available

Protocol	Site	Primary Location	Site Investigator	Site Requester
B93214		No Site - Ptd only		
B94055		No Site - Ptd only		
B94056		No Site - Ptd only		

Request Date	Status	Check In Date	Checked In Date	Reply from server

The login ID of the user whose status is being requested: 12-Aug-1999

Fig. 58

[illegible]

Fig. 59

QUERYING

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Subject Detail Report \*\* Query Made \*\*

Schering Drug	Country	Protocol No.	Site No.	Visit	Contact	Subject Enrollment Date

Ready 5/5/98 13:29:01

00555667 090600

Fig. 60

# SUBJECT SUMMARY REPORT

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Site / Subject Summary Report

**PROSIT - SITE / SUBJECT SUMMARY REPORT**

Schering No.	032088 MOMETASONE	Working Study Title	Mometasone vs. Budesonide in Athma	Protocol No. - Site No.	Q000033-1
Principal Investigator	J O ORTIZ	Study Location	ENGELWOOD, CO, UNITED STATES	Monitor	

Site 1 Details

Site Status: ENROLLMENT ONGOING # Subjects Projected: Data Collection Tool : CRF

Enrollment Summary			Milestones		Monitoring Summary	
	Site Level	Subj. Level				
# Subj. Ineligible for Screening:	0		Site Initiation Visit Date:		Total Visits Completed :	6
# Subj. Screened:	0	2	First Subject Screened:		Visits Monitored :	4 (66%)
# Subj. Failed Screening:	0	0	First Subject Enrolled:		Visits 100% SDV :	1 (16%)
# Subj. Enrolled (% Projected):	0	2	Last Subj. Enrolled to Date:		Visits Collected :	4 (66%)
# Subj. Ongoing:	0	1	Enrollment Complete:		Date of Last Contact:	25-MAR-1998
# Subj. Discontinued:	0	0	Last Subject Last Visit:		Date of Last Visit:	25-MAR-1998
# Subj. Complete:	0	1	Close out Visit:		Visits at the Site:	1

Per Subject Summary

Subject ID	Age	Gender	Date Enrolled	Status	Last Visit (phase)	Last Visit Date	Reason for Discontinuation	Eval	Date RX Started	Date RX Stopped
0001 DL 1	25Yrs	M		O	t1v1	04-FEB-1998		UN		
					SCR					

Microsoft Word - REPORT

PROSIT - NEVER NE

2:08 PM

Fig. 61

09655657 090600

# MONITORING STATUS REPORT

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Monitoring Status Report

**PROSIT - MONITORING STATUS REPORT**

Schoring No.	000088 MONETAGONE	Working Title	Monetagone vs. Submonetone in Atoms	Protocol No. / Site No.	0000000-1
Principal Investigator	J. GORTZ	Study Location	ENGELWOOD CO. UNITED STATES	Monitor	

Site 1 Summary As Of 25-Mar-1998 Site Contact No: 2626

Status		Visits		Subjects	
Protocol:	AMENDED	Completed:	6	Prepared:	
Site:	ENROLLMENT ONGOING	Screened:	4 (66%)	Actual # Screened:	2
Visits at the site:	4	100% SDV:	1 (16%)	Actual # Enrolled:	1
Date of last visit:	25-Mar-1998	Collected:	4 (66%)	Actual # Completed:	1

Site 1 Details

	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	D/C Reason
Belgian																
800V0U1	[100]	[CU]	[CU]	[1=100]												
HC 8400Y	C						C									
Comptroller	2	1	1	1	0	0	1	0	0	0	0	0	0	0	0	
Meekland	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	
Collected	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	

Legend: C = Completed; 100 = 100% SDV; CU = Key Unusually; 100 = 100% SDV; [ ] = Collected; standard = D not in hand  
V1 = last screen; V2 = screen; V3 = (1st); V4 = (1st); V5 = (1st); V6 = (1st); V7 = screen; V2

Ready 5/5/98 14:38:01

Fig. 62

009060" 29955960

## SITE PERSONNEL AND LOCATION REPORT

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Site Personnel & Locations Information Report

### PROSIT - SITE PERSONNEL & LOCATIONS INFORMATION SHEET

Sponsor No.	032068 MOMETASONE	Working Title	Mom vs Bud in Asthma
Protocol No.	AP00045 - 1	Expense Center	1763 - CLINICAL RESEARCH - ALLERGY II
Principal Investigator	J. TABASCOMINGUILLAN	Monitoring Country	Never Never Land

**NON SP PERSONNEL**

Maid, Mer	Tabascominguillan, J	Bell, Tinker
IRB CHAIRMAN	PRINCIPAL INVESTIGATOR	STUDY COORDINATOR
NNL	NNL	NNL
Active: 22-Apr-1998	Active: 22-Apr-1998	Active: 22-Apr-1998

**CENTRAL IRB/EC**

MERMAID ROCK

2 Stone Skip

NNL

**TREATMENT CENTER**

PIRATE SHIP

Out at Sea

Next

6/18/98 14:07:04

Fig. 63

009060 09655667 090600

# CONTACT INFORMATION REPORT

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Contact Information Report

## PROSIT - CONTACT INFORMATION SHEET

Schering No.	000058 NIACIN	Working Title	domestic
Protocol No.	A000001		

PROTOCOL A000001	EXTERNAL ORGANIZATIONS
CENTRE UNIVERSITAIRE DE SANTE Gunn, Mark C DE L'ESTRIE 3001 12E AVENUE Voice: 37 FAX: Quebec NORD SHERBROOKE, QUE	01200 Aerons, A L 1200 Revt street National Genetics Institute Kedmon, D 5835 Green Valley Circle # 104 FAX: 1-310-396-6610 FAX: 1-310-396-6610 Culver City USA manchest: London UK

SITE 1	SP PERSONNEL
Orvis, P C OSS SPECIALIST IL-10 IN 18D/HIV USA Active: 20-Feb-1998	Rispoli, Marc C PROJECT PHYSICIAN KEY PRODUCT MGMT. USA www.1ester.com Active: 20-Feb-1998

Gunn, Mark C  
SITE REQUESTER  
WORLDWIDE RSCH QA  
USA

Ready

2/26/98 9:52:37

FIS. 64

09655657 090600

# FORMS

PROSIT - Never Never Land

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: 000055

Pre-Study Visit No.: 2867

Pre-Study Visit: SP Person

Potential Investigator: Hook, Capt

Country: Never Never Land

Visit Date: 31-MAR-1998 Time: 11:00 Finalized: 00-0000

Schering Participants:

Pan, Peter J.  
Butt, Thud

Investigator Site Participants: Non - Registered (\*)

Deck, Hans  
Hook, Captain  
Smee, Mister

MDMETASONE

Country: Never Never Land

Evaluation

RATE SHIP

Ready 4/1/98 17:18:17

Fig.  
65

009060" 29955960